

EXHIBIT G

1 IN THE UNITED STATES DISTRICT COURT
2 FOR THE NORTHERN DISTRICT OF OHIO
3 EASTERN DIVISION

4 - - -

5
6 IN RE: NATIONAL : HON. DAN A.
7 PRESCRIPTION OPIATE : POLSTER
8 LITIGATION :
9 :
10 APPLIES TO ALL CASES : NO.
11 : 1:17-MD-2804
12 :

13 - HIGHLY CONFIDENTIAL -

14 SUBJECT TO FURTHER CONFIDENTIALITY REVIEW

15 - - -

16 April 29, 2019

17 - - -

18 Videotaped deposition of
19 KATHERINE KEYES, Ph.D., taken pursuant to
20 notice, was held at the law offices of
21 Lief Cabraser, LLP, 250 Hudson Street,
22 New York, New York beginning at 9:08
23 a.m., on the above date, before Michelle
24 L. Gray, a Registered Professional
Reporter, Certified Shorthand Reporter,
Certified Realtime Reporter, and Notary
Public.

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1 in your report?

2 A. So as I mentioned in the
3 report, there are other programs and
4 policies that counties have -- have
5 developed, have considered. I think
6 there's different levels of evidence for
7 them. I felt that these three in
8 particular had a solid evidence base
9 for -- again, not exhaustive. But these
10 three are three really solid ways to
11 reduce opioid use disorder and morbidity
12 and mortality that have evidence
13 associated with them.

14 Q. Did you think that these
15 three were the ones that had the best
16 evidence bases that you were aware of?

17 A. I would --

18 MS. RELKIN: Objection to
19 form.

20 You can answer.

21 THE WITNESS: I -- I was not
22 asked to evaluate the best
23 policies and programs. I was
24 asked to -- my approach to this

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1 report was to outline the evidence
2 for three solid programs that had
3 a strong evidence base.

4 BY MS. WINNER:

5 Q. My question is --

6 A. I'm not sure what the best
7 means. Can you --

8 Q. Well, the best evidence I
9 think, is actually, what I asked you.
10 Were those the ones that you thought had
11 the best evidence?

12 A. Not necessarily. I think
13 there's a combination of factors that one
14 needs to use and that we use in public
15 health when choosing what programs and
16 policies to highlight in these types of
17 contexts. One is the level of evidence.
18 Another is the anticipated impact.

19 So I think, you know, among
20 other reasons that one would focus on
21 particular policies, I thought these
22 three had both a solid evidence base and,
23 specific to the counties, there was
24 enough information to suggest that there

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1 would be an impact on the epidemic.

2 Q. Were there any other reasons
3 other than the ones you just described
4 why you selected these three?

5 A. I would say that evidence
6 and impact were the -- the main reasons.

7 Q. Okay. Now, I'm pretty sure
8 I know the answer to this question, but
9 I'm going to ask it anyway.

10 In evaluating these measures
11 did you -- did your analysis
12 differentiate in any way between
13 abatement measures that are needed for
14 harms that can be traced back to
15 prescription opioids versus those that
16 are attributable solely to people whose
17 abuse of heroin or other illicit opioids
18 has nothing to do with prescription
19 opioids?

20 MS. RELKIN: Objection to
21 form.

22 You can answer if you can.

23 THE WITNESS: The case that
24 I make in this report is that the

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1 increase in the supply of
2 prescription opioids under -- was
3 an underlying factor for the
4 development of additional opioid
5 epidemics, including the heroin
6 epidemic creating a market,
7 increasing the risk among users.
8 And so, I would attribute -- in
9 terms of the overall opioid
10 epidemic, I don't see how one in a
11 public health sense would
12 differentiate between those two.

13 BY MS. WINNER:

14 Q. So you don't think that
15 that's something that would be practical
16 to do, to try to differentiate between
17 those two categories?

18 A. That's not what I said. I
19 don't think one -- I think that these
20 epidemics are so intertwined in terms of
21 their underlying causation, that it's not
22 only -- the practicality of it is not the
23 key aspect. It's the level of evidence
24 for causation.

<p style="text-align: right;">Page 370</p> <p>1 Q. Now, remedial measures that</p> <p>2 are taken to address the kinds of</p> <p>3 problems that you've identified in your</p> <p>4 report are today taken by a variety of</p> <p>5 different actors, correct?</p> <p>6 MS. RELKIN: Objection to</p> <p>7 form.</p> <p>8 THE WITNESS: I don't know</p> <p>9 what you mean. Can you define</p> <p>10 remedial measures?</p> <p>11 BY MS. WINNER:</p> <p>12 Q. Well, you identify three,</p> <p>13 MAT --</p> <p>14 A. So but -- I'm sorry. Can</p> <p>15 you define remediation, what you mean by</p> <p>16 that word.</p> <p>17 Q. Well, let me change the word</p> <p>18 if that's giving you a problem.</p> <p>19 Abatement measures, does that make you</p> <p>20 feel more comfortable?</p> <p>21 A. Sure. The three policies</p> <p>22 and programs that I talk about.</p> <p>23 Q. Yes. The kinds of programs</p> <p>24 that you talk about are undertaken in the</p>	<p style="text-align: right;">Page 372</p> <p>1 treatment that vary across a wide variety</p> <p>2 of contexts.</p> <p>3 Q. And that would include MAT,</p> <p>4 correct?</p> <p>5 A. So as I've said, I am not</p> <p>6 sure what you mean by federal funding.</p> <p>7 There is federal funding for health</p> <p>8 insurance that is included in what I've</p> <p>9 outlined here.</p> <p>10 Q. So federally funded health</p> <p>11 insurance pays for some of these</p> <p>12 measures, correct?</p> <p>13 A. It depends on the -- on the</p> <p>14 context.</p> <p>15 Q. Have you ever heard of</p> <p>16 grants that are made available to local</p> <p>17 governments to pay for MAT?</p> <p>18 A. Again, I would need to see</p> <p>19 some specifics on a particular type of</p> <p>20 grant. Certainly there are a number of</p> <p>21 programs that are available to help</p> <p>22 individuals who are unfortunately</p> <p>23 addicted to opioids.</p> <p>24 Q. And there's some things that</p>
<p style="text-align: right;">Page 371</p> <p>1 world by a variety of different actors,</p> <p>2 correct?</p> <p>3 A. Can you describe what you</p> <p>4 mean by actors.</p> <p>5 MS. RELKIN: Objection to</p> <p>6 form. Overbroad.</p> <p>7 BY MS. WINNER:</p> <p>8 Q. Well, for example there are</p> <p>9 some things that the federal government</p> <p>10 implements and pays for, correct?</p> <p>11 A. Can you give me an example?</p> <p>12 I can't --</p> <p>13 Q. You're not aware of any?</p> <p>14 Are you aware of anything in these</p> <p>15 categories that the federal government</p> <p>16 pays for?</p> <p>17 A. I need -- I need some</p> <p>18 specifics in terms of what exactly you're</p> <p>19 referring to in order to answer that</p> <p>20 question.</p> <p>21 Q. Are you aware of federal</p> <p>22 funding for MAT, for example?</p> <p>23 A. There are reimbursement</p> <p>24 programs for different levels of</p>	<p style="text-align: right;">Page 373</p> <p>1 are -- some abatement measures that are</p> <p>2 undertaken at the state level, correct?</p> <p>3 A. I think that there are a</p> <p>4 broad range of institutions that can</p> <p>5 participate in reversing the opioid</p> <p>6 epidemic. What currently occurs in terms</p> <p>7 of the participation of institutions to</p> <p>8 reduce the impact of the opioid epidemic</p> <p>9 and what could possibly occur, -- what</p> <p>10 I'm addressing here is the evidence for</p> <p>11 these programs for their ability to</p> <p>12 reduce the opioid epidemic, and that's</p> <p>13 what's in the report.</p> <p>14 Q. Okay. So would it -- based</p> <p>15 on what you just said, would it be fair</p> <p>16 to say that what you've done in your</p> <p>17 analysis, is try to identify needs</p> <p>18 without necessarily evaluating who would</p> <p>19 actually satisfy those needs?</p> <p>20 A. I think what I was asked to</p> <p>21 do --</p> <p>22 MS. RELKIN: Objection to</p> <p>23 form.</p> <p>24 THE WITNESS: As an</p>

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1 All right. So in Section F,
2 this is one of the -- section -- the
3 prior -- prior section you talk about --
4 generally about the efficacy of naloxone
5 distribution. And then in Section F.5.1
6 you go on to talk about the need
7 specifically in Cuyahoga County and
8 Summit County, correct?

9 A. So the first part of
10 Section F.5 provides an evidence base for
11 the efficacy of naloxone in reversing
12 potential failed consequences of an
13 overdose. And also, in addition to that,
14 the evidence base that -- that providing
15 expanded access to naloxone also reduces
16 overdose events. So it's really two
17 different statements.

18 Q. But -- but that said, where
19 you talk specifically about the -- trying
20 to quantify needs in Cuyahoga County and
21 Summit County for naloxone, that's
22 Section F.5.1, correct?

23 A. That's correct.

24 Q. Okay. So -- and then you

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1 talk about, in that section, you give --
2 you make a number of different
3 observations about -- about the numbers
4 and the needs for naloxone.

5 But I want to focus just on
6 the first instance, in the last
7 paragraph, which is about naloxone
8 administration kits in Cuyahoga County,
9 correct?

10 A. Okay.

11 Q. And in there you say, a
12 couple sentences down -- third sentence I
13 think. This is in -- "This is in
14 addition to medical first responders such
15 as EMS who are trained to administer
16 naloxone, available data indicate that in
17 2018 Cuyahoga County EMS administered
18 naloxone at least 4,353 times."

19 And then you go on with the
20 parenthetical about that. I'm -- I'm
21 focused on this 4,353 number.

22 Does Cuyahoga County
23 actually have EMS services at the county
24 level?

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1 A. This statement was based on
2 data that was provided to me.

3 Q. By whom?

4 A. By the counsel.

5 Q. Okay. So -- by counsel, you
6 mean plaintiffs' counsel, not your
7 counsel. We know that.

8 A. That's right.

9 Q. Yes. Okay.

10 So this came from
11 plaintiffs' counsel, correct?

12 A. Yes.

13 Q. Okay. So am I correct that
14 you don't actually know yourself whether
15 Cuyahoga County provides EMS services?

16 A. I evaluated the -- the
17 statement based on what was sent to me.

18 Q. Were you assuming, based
19 on -- on the information that was
20 provided to you by counsel, that Cuyahoga
21 County itself was, in fact, providing EMS
22 services?

23 A. Again, I think what I have
24 in the report is pretty clear. You know,

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1 I was sent information -- I asked for
2 information about, you know, providing an
3 estimate of the potential impact in the
4 county and that's the information that
5 was provided to me. And that's what's in
6 the report.

7 Q. So are you purporting
8 here -- I don't want to use the word
9 purporting. That isn't --

10 MS. RELKIN: Objection to
11 form.

12 BY MS. WINNER:

13 Q. I don't -- that -- are you
14 intending here to provide an opinion
15 about the naloxone needs that exist for
16 EMS in the city of Cleveland?

17 A. What I provided was the
18 information that was given to me about
19 the number of administered naloxone
20 distribution based on the information
21 that I was sent.

22 Q. My question though, are you
23 offering any opinions through this report
24 about abatement needs in the city of

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1 Cleveland, to be provided for by the city
2 of Cleveland?

3 A. My understanding is the city
4 of Cleveland is in Cuyahoga County; is
5 that correct?

6 Q. That -- last I knew, yes.

7 A. So I would say that that is
8 covered under the estimates that I have
9 provided.

10 Q. If it were demonstrated to
11 you that Cuyahoga County, in fact, does
12 not provide EMS services, would that have
13 any impact on the opinions that you
14 provide in this paragraph?

15 A. I mean, you know, let's --
16 I'm -- I'm -- I keep an open mind to all
17 available evidence. I think the point
18 that I was making in this paragraph is
19 that naloxone is a really important
20 program to reduce overdose. And however
21 it is distributed is how it should be
22 distributed. So if there is new
23 information that I could use, my opinion
24 would not change. Just that distributing

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1 naloxone is an important thing to do in
2 Cuyahoga County.

3 Q. Well, you have basically two
4 sets of opinions about naloxone in -- in
5 this report.

6 One set of opinions is about
7 whether naloxone is a good and important
8 thing to have out there. The other set
9 of opinions is about specific numbers,
10 and so I'm trying to focus on your
11 opinions about specific numbers.

12 And so my question is:
13 If -- if -- leaving aside the question of
14 whether, you know it is important for
15 naloxone to be available in the
16 community, would your opinion about the
17 specific needs of Cuyahoga County be
18 affected if you knew that Cuyahoga County
19 does not provide EMS services?

20 MS. RELKIN: Objection to
21 form. Compound.

22 THE WITNESS: Again, I think
23 I would -- I would respond to that
24 by saying what I intended to

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1 convey in that paragraph was some
2 assessment of the overall amount
3 of distribution of naloxone that
4 should occur.

5 If there are -- if new
6 information comes to light about
7 specific EMS services, you know,
8 that estimate could be revised.
9 But it doesn't change the overall.

10 That's one sentence in the
11 overall paragraph about the
12 estimated number of naloxone
13 administration kits that I would
14 estimate would be necessary.

15 So, sure, of course, I keep
16 an open mind. If new information
17 is available, I obviously want to
18 present the most accurate picture
19 that I can. But I think the
20 opinion that I have doesn't
21 change.

22 BY MS. WINNER:

23 Q. Do you distinguish in your
24 opinion -- is there a difference in

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1 your -- let me start that again.

2 Is there a difference in
3 your view between the amount of naloxone
4 that is needed within Cuyahoga County as
5 opposed to the amount that is needed by
6 Cuyahoga County as a government entity?

7 MS. RELKIN: Objection to
8 form.

9 THE WITNESS: I need more
10 information on your
11 differentiation.

12 BY MS. WINNER:

13 Q. So you can't answer my
14 question without more information?

15 A. I don't understand your
16 question.

17 Q. Okay. Let me ask you about
18 your section about Summit County.

19 You have a similar
20 paragraph, discussing naloxone
21 administration kits in Summit County on
22 the next page, correct?

23 A. Mm-hmm.

24 Q. And do you know -- and that

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1 includes, among other things -- there are
 2 other things in here. But one of the
 3 things that's in there is you have an
 4 estimate of the amount of naloxone that
 5 is needed for EMS in Summit County,
 6 correct?

7 A. So what I have in here is,
 8 "Data are not currently available to me
 9 regarding the total number of first
 10 responders in Summit County; however, the
 11 Akron Fire Department has a current work
 12 force of approximately 354 individuals,
 13 and there are 14 EMS/paramedics," and I
 14 have a citation that was provided to me.

15 "Available data indicate
 16 that in 2018 Summit County EMS
 17 administered naloxone at least 1,562
 18 times. This is likely an underestimate
 19 because 81.8 percent of EMS agencies
 20 reported."

21 Q. Is there such a thing as
 22 Summit County EMS?

23 A. Again, I don't -- this is
 24 the information that was provided to me.

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1 If new information comes to light, it
 2 doesn't change my opinion that naloxone
 3 is very much needed in communities that
 4 have a high burden of opioid overdose.

5 Q. You say this was information
 6 that was provided to you. Again, was it
 7 provided to you by plaintiffs' counsel?

8 A. That's correct.

9 Q. You -- in what you just
 10 read, there's a reference to the Akron
 11 Fire Department.

12 A. Yes. The Akron Fire
 13 Department has a current --

14 Q. I don't need you to read it
 15 again. Is the Akron Fire Department an
 16 agency of the Summit County government?

17 A. This is the information that
 18 was provided to me. I can -- we can go
 19 to Reference 195 and look at the
 20 information.

21 I asked plaintiffs' counsel
 22 for information on these different
 23 workforce numbers. And these are the
 24 numbers that I relied on. Should new

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1 information come to light, again, the
 2 opinion is the opinion. I think
 3 providing an estimate for these specific
 4 counties is -- is what I was endeavoring
 5 to do in these paragraphs.

6 Q. Do you know whether the
 7 Akron Fire Department carries naloxone
 8 today?

9 A. That information was not
 10 provided to me.

11 Q. If -- well, I assume the
 12 answer is going to be the same. But let
 13 me just ask it.

14 Assuming that the Akron Fire
 15 Department does carry naloxone, do you
 16 know who pays for it?

17 A. In the -- I'm sorry, this
 18 pen is really leaking.

19 In the information that was
 20 provided to me, the source of funding for
 21 each individual naloxone kit was not
 22 included.

23 Q. Now, in Section C.3 of your
 24 report -- let's go back. It starts on

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1 Page 32. You provide estimates of the
 2 numbers of persons in each of these two
 3 counties who were currently living with
 4 opioid use disorder, correct? I'll
 5 direct you to the last paragraph on Page
 6 32, the first sentence.

7 A. Yes. "While the number of
 8 individuals currently living with opioid
 9 use disorder in Cuyahoga and Summit
 10 Counties is unknown, I can provide an
 11 estimate of the number, given number the
 12 overdose deaths."

13 Q. And you -- is the estimate
 14 that you then -- and we'll walk through
 15 this. But is the estimate that you then
 16 go on to provide intended to be
 17 specifically an estimate of the number of
 18 individuals in each county who is
 19 currently living with opioid use
 20 disorder?

21 A. Depend -- so the paper that
 22 I relied onto make that assessment looked
 23 at individuals who were dependent or
 24 regular users of opioids.

<p style="text-align: right;">Page 390</p> <p>1 Q. Is that the same thing as 2 people who have opioid use disorder? 3 A. So this is the information 4 that I thought was important to gather an 5 estimate of the number of individuals who 6 would be in need of these services. 7 Q. But my question is -- 8 A. It would be inclusive of 9 opioid use disorder. 10 Q. But is opioid use disorder 11 the same thing as being a dependent or 12 regular user of opioid? 13 A. So the Degenhardt, et al., 14 2011 paper did not is assess opioid use 15 disorder. The Degenhardt paper assessed 16 dependent or regular users of opioids. 17 And I used that paper to provide an 18 estimate of the number of individuals in 19 those counties who would be in need of 20 these services, and would include 21 individuals living with opioid use 22 disorder. 23 Q. Is it limited to people who 24 have opioid use disorder or is it</p>	<p style="text-align: right;">Page 392</p> <p>1 Keyes-13.) 2 BY MS. WINNER: 3 Q. And is Exhibit 13 in fact 4 the article that you referred to a second 5 ago as the one that you relied upon for 6 this calculation? 7 A. So this article, just to be 8 clear, is a random effect meta-analysis 9 for the mortality, the crude and 10 standardized mortality rates for 11 individuals who are dependent or regular 12 users of opioids. 13 Q. Okay. 14 A. And I relied on it for this 15 assessment. 16 Q. Okay. And this is -- this 17 is the article that you cite in this 18 section of your report? I think it's -- 19 A. I cite this article in this 20 section of the report. 21 Q. And it is, I think, just for 22 the record, this is Reference 151. 23 A. Let me just double-check 24 that.</p>
<p style="text-align: right;">Page 391</p> <p>1 broader? 2 A. The estimate is individuals 3 who are dependent or regular users of 4 opioids. 5 Q. Is that likely to be 6 broader, narrower, or the same as the 7 population of people with opioid use 8 disorder? 9 A. Let's see. Individuals who 10 are dependent, so -- and regular users of 11 opioids. I would estimate that it's 12 largely similar. 13 Q. How similar? Do you have a 14 confidence interval or anything like that 15 for that? 16 A. I would need to do a 17 statistical analysis for that. 18 Q. Okay. I'd like to show you 19 what's been previously marked as 20 Exhibit 13 to your deposition, which I'm 21 hoping is the article that you're talking 22 about. 23 (Document marked for 24 identification as Exhibit</p>	<p style="text-align: right;">Page 393</p> <p>1 Q. Sure. 2 A. Yes, it is Reference 151. 3 Q. What you pulled out of this 4 report, am I correct -- well, first of 5 all, let's just talk about what this is. 6 This is a -- and I don't 7 want to go into every detail of it. But 8 generally this is a review of multiple 9 studies that evaluates their results on 10 the subject of mortality, correct? 11 A. So the outcomes reported 12 here are two outcomes. One is the crude 13 mortality rate. And one is the 14 standardized mortality rate for specific 15 causes of death across studies that used 16 inclusion criteria -- I'm sorry, that 17 used exclusion criteria that included not 18 reporting heroin or opioid users, 19 opioid-related mortality, or not reported 20 research data or case studies. 21 So that is what the design 22 was, was a multiple search strategy to 23 find studies that assessed mortality 24 among regular and dependent users of</p>

<p style="text-align: right;">Page 398</p> <p>1 that any one particular study, you might 2 be over or slightly under due to random 3 error or, you know, any number of 4 different reasons. And so in a 5 meta-analysis, what you do is take all 6 the studies on a particular topic and 7 then provide a summary estimate of them. 8 That is the intention of the analysis. 9 Q. And -- and you would 10 consider this an epidemiological -- I can 11 never pronounce that word. You are 12 obviously used to it. 13 For your field, this is an 14 epidemiological study, or analysis, or 15 review, or whatever the word would be? 16 This is in your -- this comes from your 17 field, this particular paper here? 18 A. I guess my question is, what 19 do you mean by my field? 20 Q. Well, you are an 21 epidemiologist, correct? 22 A. I am an epidemiologist, yes. 23 Q. And -- and is this a paper 24 from epidemiology?</p>	<p style="text-align: right;">Page 400</p> <p>1 So your question is? 2 Q. I'm just trying to translate 3 that into more everyday English. Does 4 that mean that -- 5 A. If 100 people were observed 6 for one year, you would expect there to 7 be .65 overdose deaths. 8 Q. Thank you. That's helpful. 9 And that is the -- that .65 10 figure is the number that you then went 11 on to use to apply to overdose statistics 12 to estimate the populations in each of 13 those -- these who had counties overdose 14 related -- 15 A. I used that as a -- and its 16 related confidence interval, to provide 17 an estimate of the number of dependent or 18 regular users of heroin -- I mean of 19 opioids. 20 Q. Now, the -- who are the -- 21 the subjects of these studies? Is -- and 22 I'm not asking you to list them all. Am 23 I correct that they are described in the 24 tables that -- the table that starts, I</p>
<p style="text-align: right;">Page 399</p> <p>1 A. I would say that this paper 2 uses epidemiological studies in order 3 to -- you know, meta-analysis is used -- 4 a lot -- I wouldn't claim it for 5 epidemiology. But this particular paper 6 uses epidemiological data. 7 Q. So this -- am I correct 8 that, that what this paper is finding is 9 that there were .65 deaths per 100 person 10 years during which the subjects of the 11 studies were observed? 12 A. I'm sorry, I'm just going to 13 go to the place where that is written. 14 Can you point again to the 15 page number? 16 Q. Sure. Page -- it's -- we're 17 on Page 45. 18 A. Sorry. 19 Okay. So what this study 20 said in the results section is that 21 "pooled estimates suggested that overdose 22 related mortality was the most common 23 specific cause at .65 deaths per 100,000 24 person years."</p>	<p style="text-align: right;">Page 401</p> <p>1 guess it's on Page 35, Table 1? 2 A. Okay. So Table 1 is 3 included... studies investigating all 4 cause mortality. 5 And so table 2 then is 6 cohorts purporting proportion of deaths 7 due to AIDS, overdose, suicide, and 8 traumatic causes of death. 9 Q. I'm -- I'm more focused on 10 the nature of the -- I think it's the 11 nature of the sample column. 12 No, who -- who were the 13 people who were in these studies? 14 MS. RELKIN: Objection. 15 Form. Overbroad. 16 There's multiple studies. 17 Do you want her to go through each 18 one? 19 BY MS. WINNER: 20 Q. Do you see on Table 1 21 there's a column that says nature of 22 sample? 23 A. So -- yeah, you know, again, 24 I -- you really should look at Table 2,</p>

<p style="text-align: right;">Page 406</p> <p>1 the report the way the methodology</p> <p>2 is used. The methodology that I</p> <p>3 used is standard practice in the</p> <p>4 epidemiological literature.</p> <p>5 As far as any one particular</p> <p>6 study that has used this estimate</p> <p>7 in and of itself, I don't have a</p> <p>8 specific citation in the report.</p> <p>9 But it is a standard way to</p> <p>10 evaluate population sizes in the</p> <p>11 epidemiological literature.</p> <p>12 BY MS. WINNER:</p> <p>13 Q. Okay. But I want to follow</p> <p>14 up on what you just said. You don't have</p> <p>15 a specific -- I don't have a specific</p> <p>16 citation in the report, but it is a</p> <p>17 standard way to evaluate population sizes</p> <p>18 in the epidemiological literature.</p> <p>19 I just want to focus -- when</p> <p>20 you say it is a standard way, are you</p> <p>21 talking about --</p> <p>22 A. I'm talking about the method</p> <p>23 and not this particular number.</p> <p>24 Q. Got it.</p>	<p style="text-align: right;">Page 408</p> <p>1 A. That's correct.</p> <p>2 Q. And the overdose death</p> <p>3 statistics from those counties that you</p> <p>4 used included all drug overdoses, not</p> <p>5 just opioid overdoses, correct?</p> <p>6 A. So just to be clear, that</p> <p>7 is -- the reason for that is because the</p> <p>8 Degenhardt meta-analysis looked at all</p> <p>9 drug overdose deaths among regular or</p> <p>10 dependent users. And so to provide a</p> <p>11 comparable analysis, I needed to use all</p> <p>12 drug overdose deaths in the counties.</p> <p>13 Q. But those were all drug</p> <p>14 overdose -- okay. Strike that.</p> <p>15 Let me try to streamline</p> <p>16 this a little bit. Let's go back to</p> <p>17 Degenhardt. Is that an appropriate way</p> <p>18 to refer to Exhibit 13. If you would</p> <p>19 turn back to the abstract. Near the</p> <p>20 bottom there is a sentence that reads, "A</p> <p>21 multi-variable regressions found the</p> <p>22 following predictors of mortality rates:</p> <p>23 Country of origin, the proportion of</p> <p>24 sample injecting, the extent to which</p>
<p style="text-align: right;">Page 407</p> <p>1 MS. DO AMARAL: Counsel, is</p> <p>2 it a good time for us to take a</p> <p>3 break?</p> <p>4 MS. WINNER: Sure, no</p> <p>5 problem.</p> <p>6 THE VIDEOGRAPHER: The time</p> <p>7 is 4:18 p.m. Going off the</p> <p>8 record.</p> <p>9 (Short break.)</p> <p>10 THE VIDEOGRAPHER: The time</p> <p>11 is 4:32 p.m. Back on the record.</p> <p>12 BY MS. WINNER:</p> <p>13 Q. Okay. Before the break, we</p> <p>14 were discussing the calculations you did</p> <p>15 in Section C.3 of your report.</p> <p>16 A. Yes.</p> <p>17 Q. Correct?</p> <p>18 And am I correct that you</p> <p>19 took this .65 per 100 person-year number,</p> <p>20 and you then applied that to the overdose</p> <p>21 deaths in 2013 in each of the two</p> <p>22 counties to estimate the opioid dependent</p> <p>23 or regular user population in each</p> <p>24 county?</p>	<p style="text-align: right;">Page 409</p> <p>1 populations were recruited from an entire</p> <p>2 country versus sub-national, and year of</p> <p>3 publication."</p> <p>4 Did I read that correctly?</p> <p>5 A. You read that statement</p> <p>6 correctly. I'd like to go just to the</p> <p>7 methods section to make sure that --</p> <p>8 because sometimes in abstracts it's an</p> <p>9 oversimplification of what was done.</p> <p>10 Q. Okay. Is there something</p> <p>11 inconsistent? I assume you studied this</p> <p>12 study fairly carefully before you used</p> <p>13 it.</p> <p>14 A. I did study -- I did study</p> <p>15 it carefully, but with over 200</p> <p>16 citations, I just want to be sure that we</p> <p>17 don't abstract something from an abstract</p> <p>18 that is defined more carefully in the</p> <p>19 paper itself.</p> <p>20 Okay. So on page 43, I</p> <p>21 think they provide more information on</p> <p>22 study covariates. So the proportion of</p> <p>23 the sample injecting was included in the</p> <p>24 covariate as a continuous variable at a</p>

<p style="text-align: right;">Page 410</p> <p>1 bivariable level. Study is conducted in 2 countries low and middle income. Low 3 case ascertainment. High percentage of 4 sample injecting. 5 So yes. 6 Q. All right. Then there's a 7 section called "Limitations" on Page -- 8 starting on Page 46. I've seen a section 9 entitled "Limitations" in a number of the 10 studies that you've cited. Is that a 11 common section to include in an article 12 like this? 13 A. Yes. 14 Q. And what is the author 15 generally -- what is the purpose of a 16 Limitations section in a paper like this? 17 A. Generally, in 18 epidemiological studies, the purpose of a 19 limitations section is to provide the 20 reader with any additional information 21 that would aid in their interpretation of 22 the paper and to provide an opportunity 23 for the author to provide additional 24 information on the robustness of their</p>	<p style="text-align: right;">Page 412</p> <p>1 there is heterogeneity, to use that word 2 again, there are differences in the 3 length of follow-up of the cohorts from 4 one to 36 years. 5 When you meta-analyze 6 something, you're aggregating across all 7 of that. 8 Q. Sometimes when you aggregate 9 over a heterogenous set of data, you can 10 gloss over variations, meaningful 11 variations within the data, correct? 12 MS. RELKIN: Objection to 13 form. 14 THE WITNESS: So anytime we 15 provide, you know, this is what 16 epidemiology does. We provide 17 aggregate estimates of risk. We 18 don't provide estimates at the 19 individual level. So we're always 20 aggregating to provide an 21 assessment of risk factors. 22 You know, the overdose 23 deaths in the counties are also an 24 aggregate of a lot of individuals.</p>
<p style="text-align: right;">Page 411</p> <p>1 results to any particular limitation of 2 the methods, data source, et cetera. 3 Q. Well, the first paragraph 4 under limitations here says that, "The 5 studies reviewed here differed 6 considerably. The length of follow-up of 7 the cohorts ranged from one to 36 years. 8 This is problematic, because drug use can 9 change over time period, and this can 10 affect mortality rates." 11 I'll stop there. 12 Do you think that that is an 13 accurate statement of a limitation of 14 this review? 15 A. I would say that -- I would 16 say that that is an accurate limitation 17 of the review. But again, applying it in 18 the way that I did in the report, I think 19 you provide a confidence interval around 20 the estimate. You know, that's the best 21 available estimate for the rate of the 22 standardized mortality ratio for a 23 dependent user. 24 So I think that even though</p>	<p style="text-align: right;">Page 413</p> <p>1 BY MS. WINNER: 2 Q. But aggregation can be -- 3 the reason heterogeneity is identified as 4 a limitation here, is because, or at 5 least in part because aggregate -- it 6 means that aggregation can yield results 7 that are less meaningful? 8 A. I don't necessarily think 9 that that is -- it really depends on what 10 the research question you're asking is 11 and what you're using those data for, in 12 terms of the meaningfulness of 13 aggregation. Sometimes we want an 14 aggregate estimate of the average risk of 15 a certain outcome across the heterogenous 16 subgroups that make up that average risk. 17 Q. Have mortality rates from 18 overdose deaths in the drug using 19 population changed over time? 20 A. Over what time period 21 specifically? 22 Q. Over any time period over 23 the last 20 years? 24 A. So specifically in the last,</p>

<p style="text-align: right;">Page 414</p> <p>1 you know, three years since 2013, 2 mortality rates have increased. 3 Q. And did mortality rates 4 change in the time period before the last 5 three years? 6 A. The mortality rates, the 7 overall population mortality rate due to 8 overdose has changed. Is your question 9 about changes over -- can you be specific 10 about the population with which you're 11 asking the question. 12 Q. Okay. That's a fair 13 question. Let's start with the overall 14 population mortality rate has changed 15 over time, has it not? 16 A. The overall population 17 mortality rate of -- 18 Q. For overdose? 19 A. For overdose has increased. 20 Q. Has the overall mortality 21 rate varied over time before the past 22 three years among opioid users? 23 A. You know, I would have to go 24 to meta-analysis in order to answer that</p>	<p style="text-align: right;">Page 416</p> <p>1 California. One is based in Albuquerque. 2 One is among Vietnam veterans. And 3 overall it does not provide data on 4 whether the overdose rate among those 5 different populations have changed over 6 time. 7 So as far as I know, you 8 know, the -- the overdose rate among 9 regular or dependent users of opioids in 10 the United States has not been 11 systematically investigated. 12 Q. Now, you do however have an 13 opinion that the mortality rate has 14 changed in the past three years because 15 of the fentanyl problem? 16 A. The population mortality 17 rate has. 18 Q. The population mortality. 19 Is that also true of the -- 20 the opioid using population mortality 21 rate? 22 MS. RELKIN: Objection to 23 form. 24 THE WITNESS: So I'm sorry,</p>
<p style="text-align: right;">Page 415</p> <p>1 question. 2 You're asking about the 3 United States? 4 Q. Yes. 5 A. So let's see if there are 6 U.S. studies -- 7 Q. Well, let me just ask, is 8 that something you've looked at before I 9 asked you that question just now? 10 A. What the variation over 11 time -- so what I used as a meta-analysis 12 that pooled data across a number of 13 different studies. To the extent that 14 there are U.S. studies involved in that 15 particular estimate, I don't believe that 16 there are, but I would like to just 17 confirm. 18 So the meta-analysis used 19 three different studies from North 20 America, from the United -- no, I'm 21 sorry, four different studies -- I 22 apologize again. No, that's from Canada. 23 So there are a number of 24 studies cited in here. One is based in</p>	<p style="text-align: right;">Page 417</p> <p>1 your question is whether there is 2 available data on the overdose 3 rate from fentanyl among opioid 4 users? 5 BY MS. WINNER: 6 Q. Let me -- let me -- let me 7 take a step back and ask a different 8 question. 9 If the -- some opioids, if 10 abused, are more lethal than others, 11 correct? 12 A. It depends on the amount, 13 the dose, and the duration of use. 14 Q. But -- but in terms of -- 15 A. I wouldn't make -- I just -- 16 I wouldn't make a blanket statement about 17 products and their overdose potential. 18 Q. Well, do you believe, based 19 on the data you've seen that illicitly 20 manufactured and sold fentanyl that's 21 used to adulterate heroin and cocaine and 22 other drugs, is -- contributes to more 23 overdose deaths than abuse of Vicodin for 24 example?</p>